DETAILED ACTION

The Reply filed by Applicants on 06/23/2011 is hereby acknowledged. Claims 1-3, 7, 10-11, 14-16, 19, 25, 30, 39, 43-46, 54, 56-62, 89-90, 93 and 96 are pending and examined herein on the merits.

Claim Rejections - 35 USC § 101

Applicant's arguments, see pages 11-12 of response, filed 06/23/2011, with respect to nonstatutory subject matter have been fully considered and are persuasive when taken together with the claim amendments. The rejection of the claims under 35 USC 101 for being drawn to non-statutory subject matter has been withdrawn.

Claim Rejections - 35 USC § 112-enablement

Claims 1-3, 7, 10-11, 14-16, 19, 25, 30, 39, 43-46, 54, 56-62, 89-90, 93 and 96 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a plant comprising any minichromosome of any size below 1000 kilobases comprising SEQ ID NO:24 or a nucleic acid sequence with 95% identity to SEQ ID NO:24 in any copy number wherein the mini-chromosome is functional, stable, autonomous and has a transmission efficiency of 90%.

In contrast, the specification provides guidance for specific BAC clones containing specific arrangements of known centromere repeats for use as centromeric

DNA, specific telomeric repeats, and specific origin of replication sequences for function as a minichromosome. The specification does not give guidance for any minichromosome with any DNA composition as broadly claimed or any number of repeats of SEQ ID NO:24 wherein the sequence confers the ability of segregating to daughter cells to the mini-chromosomes, nor does the specification indicate which sequences are absolutely required for centromere function, telomere function or origin of replication function to enable one of skill in the art over the full scope of the claims. For example, no centromere contributions under about 50kb in length are shown to function as centromeres in a minichromosome in a plant cell.

A recent article (2010, Tek et al Chromosome Research 18:337-347)on soybean centromeres (SEQ ID NO:24 is a soybean centromeric repeat) discloses the sequences believed to be necessary for centromere function in soybeans and disclose that 3 distinct repeats appear to be necessary for centromere function, GmCent-1, GmCent-4 and GmCR and state "it appears that soybean centromeres are primarily composed of two satellite sequences with relatively fewer interruptions by retrotransposon-related elements. Further investigations are required to determine the composition and contribution of GmCR elements in soybean centromeres" (see page 345 end of column 1 and beginning of column 2). It is of note that this study did not merely map the location of these repeats but did so in conjunction with the localization of CENH3 and showed interaction of CENH3 with said sequences and further, state "CENH3 is at the foundation of a complex network of proteins that forms a functional kinetochore" (see page 340, last paragraph). This study shows that the location of a sequences in the

centromeric region is not sufficient to confer centromere function and that further, it is possible that more than one sequence that interacts with CENH3 may be necessary for kinetochore formation in soybeans.

The instantly claimed sequence is of the GmCent-1 family.

Given the state of the art at the time of filing, the breadth of the claims, the lack of working examples and the unpredictability it would have been undue experimentation for one of skill in the art to evaluate sequence composition, copy number and further, to evaluate such unknown sequences in resultant plants for use as mini-chromosomes with 90% transmission efficiency rate as claimed. The required sequences were unknown in the art at the time of filing and not supplied in the instant application, and so the claims as currently written are not enabled for mini-chromosome function in any plant species including glycine max.

It is suggested that if a particular sequence composition that is disclosed in the instant application was shown to function as an autonomous mini-chromosome and fit the sequence criteria laid out in Tek et al, that the claims should be limited to this sequence composition for enablement consideration.

Response to Arguments

Applicant's arguments filed 06/23/2011 have been fully considered but they are not persuasive.

Applicants urge that Tek et al did not test the ability of the identified sequences to segregate to daughter cells and relied instead on the binding of the sequences to

CENH3, which may not be sufficient to give guidance to the sequences that confer centromeric function (See pages 8-9 of response).

This is not persuasive, because the rejection is based on the unpredictability in the field as demonstrated by Tek. The test of enablement is not whether or not Tek et al fully tested their sequences, but rather whether the instant specification provides sufficient guidance for one of skill in the art to make and use the invention commensurate in scope with the claims. In the instant case, Tek et al suggests at least 3 sequences are necessary for centromere function, while the instant specification only gives guidance to one of those sequences. While the instant specification may enable one to perform methods to identify sequences that may have centromeric function and therefore confer the ability to segregate to daughter cells, the instant specification does not provide guidance that would lead one of skill in the art to any kind of conclusion on sequence composition beyond comprising SEQ ID NO:24. Since the art indicates that more than SEQ ID No:24 is required for centromere function, and the specification does not give guidance as to what other sequences are required, the specification only provides guidance for using the BACs that are demonstrated to segregate to the daughter cells, and does not provide sufficient guidance for one to predict which products would or would not have functional centromeres.

Applicants urge that the invention as presently claimed is fully enabled based on the sequence analysis of the SB12-derived mini-chromosome as well as SB6 (see page 10 of response).

This is not persuasive because both of the above minichromosomes comprise additional sequences which the claims as currently written, are not limited to. Since one of skill in the art at the time of filing would not have been able to discern which of those sequences were necessary and which were not, the claims as currently written are not fully enabled.

Applicants urge that the Office has mis-applied a post-filing reference in the enablement rejection and quotes the MPEP stating "for which the MPEP gives clear guidance" (see page 10 of response).

This is not persuasive because the post-filing date art in question is actually demonstrated what was not known in the art at the time of filing, and is still not known in the art as of the date of the publication, and that is, namely, which sequences are required for centromere formation and function. In the instant case, Applicants have used a sequence that localizes to the centromere to isolate and identify BAC inserts that when used in plant transformation will segregate to the daughter cells as autonomous vectors. However, Applicants have not adequately differentiated between which inserts are likely to function in this way, and which ones are not likely to function in this way, only requiring that the inserts have SEQ ID NO:24 or a sequence with 95% identity to SEQ ID NO:24. Tek et al indicates that SEQ ID NO:24 is not likely to be the only required sequence for such function, and therefore when determining whether one has a product of the instant invention or not, one must be able to determine by structure which embodiments are functional and which are not, particularly when the claims are drawn to products.

Claim Rejections - 35 USC § 112-written description

Claims 1-3, 7, 10-11, 14-16, 19, 25, 30, 39, 43-46, 54, 56-62, 89-90, 93 and 96 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a plant comprising any minichromosome of any size below 1000 kilobases comprising SEQ ID NO:24 or sequences with 95% identity to SEQ ID NO:24 in any copy number wherein the mini-chromosome is functional, stable, autonomous and has a transmission efficiency of 90%.

In contrast the specification does not provide any working examples of autonomous mini-chromosomes segregating in the daughter cells of any plants. The specification does not describe all the necessary sequences for such autonomous and segregation function and does not describe what is required for the claimed function.

While the specification does describe BAC clones that comprise sequences that retain the ability to segregate in daughter cells, the specification does not fully describe the required sequences within the BAC clones that are required for centromere function.

The genus claimed, literally any sequence of any size comprising sequences with as little as 95% identity to SEQ ID NO:24 encompasses literally millions of

embodiments, particularly wherein the other sequence elements are unspecified and unknown. There are no working examples, however of autonomous mini-chromosomes in plants with at least 90% transmission efficiency. In the absence of working examples the specification should at least describe the required structural features that are necessary for the claimed function. The specification describes obtaining a consensus sequence for one type of repeat, but does not describe the other repeats that appear to be necessary for soybean centromere function as discussed in the above enablement rejection.

Accordingly, the specification as currently written lacks adequate written description for the claims are currently written.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

> [T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Response to Arguments

Applicant's arguments filed 06/23/2011 have been fully considered but they are not persuasive.

Applicants urge that the specification fully describes sequences comprising SEQ ID NO:24 wherein the sequences are comprised by an autonomous, circular mini-chromosome (see pages 10-11 of response).

This is not persuasive because the example neither demonstrates, indicates or discusses transmission efficiency, and therefore does not meet the 90% transmission rate required by the claims, nor does the specification indicate what sequence structures are required for this transmission efficiency rate.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT T. PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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